

REMARKS

The Examiner provides two rejections that are listed below in the order in which they are addressed.

- I. Claims 1-3 are rejected under 35 USC § 103(a) as allegedly unpatentable over United States Patent Application Publication No. 2002/0147196 To Quessy et al., in view of Zakrzewska et al. *J. Neurol Neurosurg Psychiat* 52:472-476 (1989).
- II. Claims 1-3 are rejected under 35 USC § 112 ¶ 2 as allegedly being indefinite.

As a preface to the following argument, the Applicants acknowledge that the Examiner has previously admitted that Quessy et al. is not an anticipatory reference:

Quessy et al. do not expressly illustrate an example of the composition comprising bupropion and oxcarbazepine ...

Office Action Mailed July 28,, 2005 pg. 3, and the Examiner has again reflected this admission in the present Office Action:

However, Quessy et al.'s illustrated composition (example 3) uses lamotrigine with bupropion, rather than oxcarbazepine as instantly claimed.

Office Action, pg. 5. Consequently, the Examiner has the burden of showing that Quessy et al. & Zakrzewska et al. provide sufficient teachings to create a *prima facie* case of obviousness. The Applicants argue below that these references, when taken together, do not provide these teachings.

I. Claims 1-3 Are Not Obvious

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the reference(s) themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the

reference. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991); and *MPEP* § 2142; Establishing A *Prima Facie* Case Of Obviousness. The Examiner is reminded that if ONLY ONE of the above requirements is not met, then a *prima facie* case of obviousness does not exist. The Applicants submit that the Examiner's rejection does not meet these criterion. The Applicants rebut the establishment of a *prima facie* case of obviousness by the argument below.

A. There Is No Motivation To Combine The Teachings Of Quessy et al. And Zakrzewska et al.

The Examiner offers Quessy et al. and Zakrzewska et al. in combination to reject Claims 1-3 on the basis of obviousness. The Applicants disagree because the Examiner has made the conclusion that there is allegedly a motivation to combine the teachings of Quessy et al. and Zakrzewska et al without a proper showing of evidence:

The mere fact that the prior art could be modified in the manner proposed by the Examiner would not have made the modification obvious unless the prior art suggested the desirability of the modification.

Ex parte Dussard, 7 USPQ2d 1818, 1820 (Bd. Pat. App. & Int., 1988). The Examiner is reminded that the presently claimed embodiment encompasses a composition comprising a drug combination. The Examiner has not shown that Zakrzewska et al. suggests any desirability to provide any drug combination. Instead, the Examiner only repeats unrelated facts regarding the administration of oxcarbazepine alone:

It would have been obvious to one of ordinary skill in the art to modify the composition of Quessy et al. ... [because] ... Zakrzewska et al. also teach that oxcarbazepine has no side effects ...

Office Action pg 6. The Examiner is reminded that the presently claimed embodiment is a composition claim, thereby making arguments based upon “methodological considerations” irrelevant.

Further, Quessy et al. provides no motivation to one having ordinary skill in the art to consider giving oxcarbazepine alone (as is taught in Zakrzewska et al.). In fact, the Examiner points to the exact teachings within Quessy et al. which demonstrates that the teachings of Quessy et al. should NOT be combined with the teachings from Zakrzewska et al:

Quessy et al. additionally teach that the composition ... [i.e., a combination of bupropion and lamotrigine] ... manifests **synergism**^[1] ...

Office Action pg 5 [emphasis in original]. When considering this synergistic teaching of a drug combination by Quessy et al., one would not be motivated to consider a single drug administration as taught in Zakrzewska et al.

Consequently, the Applicants have shown that Quessy et al. and Zakrzewska et al. are improperly combined and respectfully request that the Examiner withdraw this rejection.

B. Quessy et al. And Zakrzewska et al. Do Not Teach All The Claimed Elements

As noted above, the Examiner admits that Quessy et al. does not teach a composition comprising a combination of oxcarbazepine and bupropion. Further, despite the Examiner's assertion that Quessy et al. mentions oxcarbazepine as a sodium channel blocker, it is clear that this brief mention would be considered only "obvious to try" by the Federal Circuit and does not support an obviousness rejection:

An invention is 'obvious to try' 'where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful.'

In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673,1681 (Fed. Cir. 1988); and *Merck & Co., Inc. v. Biocraft Laboratories, Inc.*, 10 USPQ 2d 1843, 1845 (Fed. Cir. 1989). Quessy et al. provides no direction and/or critical parameters as how to choose between the many sodium channel blockers.

Also, as discussed above, it is clear that Zakrzewska et al. does not teach any drug combinations, much less a composition comprising bupropion and oxcarbazepine.

Consequently, the Applicants have shown that Quessy et al. and Zakrzewska et al. do not teach all the claimed elements and respectfully request that the Examiner withdraw this rejection.

¹ The Examiner is reminded that the Federal Circuit considers the chemical arts "unpredictable", thereby making inappropriate the application of this conclusion to a bupropion/oxcarbazepine drug combination without empirical evidence. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993).

C. Quessy et al. And Zakrzewska et al. Do Not Teach A Reasonable Expectation Of Success

The Examiner twice makes specific conclusions regarding “expectations of success”, but neither has any relevance to the presently claimed embodiment:

There is a reasonable expectation of successfully treating neuropathic pain without side effects ...

Office Action, pg 6, and

... there would have been a reasonable expectation of successfully improving the anti-neuropathic pain composition of Quessy et al. ... without ... side effect.

Office Action, pg. 7. The Examiner has not shown that either Quessy et al. or Zakrzewska et al. contain any reasonable expectation of success regarding a successful composition comprising bupropion and oxcarbazepine. The Examiner is reminded that this showing must contain an explicit prediction within the cited references:

The expectation of success must come from the prior art and explicitly predict that the process recited in the claims would work.

In re O'Farrell, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988). In fact, Quessy et al. provide caution that the success of any drug combination composition is subject to testing and verification (i.e., compounding is an empirical process):

When combined in the same formulation it will be appreciated that the two compounds must be stable and compatible with each other and the other components of the formulation.

Quessy et al. ¶ 14 [emphasis added]. The Examiner has not pointed to any evidence within Quessy et al. discussing this apparent requirement for bupropion/oxcarbazepine chemical compounding.

Consequently, the Applicants have shown that Quessy et al. and Zakrzewska et al. do not teach reasonable a expectation of success and respectfully request that the Examiner withdraw this rejection.

II. Claims 1-3 Are Clear


The Examiner states that Claims 1-3 are indefinite because "The term "derivatives recited in claim 1 render the claims indefinite". *Office Action*, pg. 3. The Applicants disagree because chemical derivatives have been long understood by those having ordinary skill in the art. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claim 1 by deleting the claim limitation regarding bupropion derivatives. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Applicants, therefore, respectfully request that the Examiner withdraw the present rejection.

CONCLUSION

The Applicants believe that the arguments and claim amendments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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